November 9, 2023

SPM Medicare Pvt. Ltd.
Sanjay Kumar
Deputy Manager
B-40, Phase II
Noida, Gautam Budh Nagar, Uttar Pradesh 201305
India

Re: K231724
Trade/Device Name: Flush Syringe (Prefilled 0.9% normal saline solution)
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: NGT
Dated: June 13, 2023
Received: June 13, 2023

Dear Sanjay Kumar:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices

OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231724

Device Name
Flush Syringe (Prefilled 0.9% normal saline solution)

Indications for Use *(Describe)*
Flush Syringe (Prefilled 0.9% normal saline solution) is intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Summary
K231724

This 510K summary is being prepared in accordance with the requirements of Title 21, CFR Section 807.92.

a) Submitter Information:

Submitter : SPM Medicare Pvt. Ltd
B-40,Phase II
Gautam Budh Nagar
Noida -201305,Uttar Pradesh, India

Contact Person: Mr. Umang Mathur
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Designation Submission

Correspondent Primary Contact Person: Sanjay Kumar
Position: Deputy Manager-QA & MR
Tel: +91-8384011434
Email : sanjay.qa@spmmedicare.com

Date of Preparation : 11-08-2023

b) Device Information:

Trade or Proprietary Name:	Flush Syringe (Prefilled 0.9% normal saline solution)
Common or Usual Name:	Pre-Filled Normal Saline Flush Syringe
Classification Name:	Saline, vascular access flush
Product Code:	NGT
Regulation Number:	880.5200
Device Classification:	II
Review Panel:	General Hospital

c) Identification of Legally Marketed Device(s):

Flush Syringe, 510K number K183473.

d) Device Description:

Flush Syringe (Prefilled 0.9% normal saline solution) is a polypropylene plastic syringe filled with 0.9% sodium chloride for injection, USP, and capped with a polypropylene syringe tip cap. The Flush Syringe (Prefilled 0.9% normal saline solution) consists of barrel, plunger, gasket and thread stopper which is used after the intended purpose is achieved to cover the barrel tip of the device. The Flush Syringe (Prefilled 0.9% normal saline solution) is sterile, non-pyrogenic and for single use.

e) Indications for Use:

Flush Syringe (Prefilled 0.9% normal saline solution) is intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices.

f) Technological Characteristics Comparison:

Intended use: The subject device has the same intended use as the predicate device.

Comparison between subject device and predicate device.

Table 5-1

Device Characteristic	Subject device	Predicate device (K183473)	Discussion
Indications for Use	The Flush Syringe (Prefilled 0.9% normal saline solution) is intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices.	The AMSafe 0.9% sodium chloride pre- filled normal saline flush syringe, is intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices. Use according to the recommend at ions of the manufacturer for the appropriate device.	Identical
Operation Principle	The Flush Syringe (Prefilled 0.9% normal saline solution) is a three-piece, sterile, single use syringe with a 6% (Luer) connector pre-filled with 0.9% Sodium Chloride Injection, USP, and sealed with a tip cap.	The AMSafe® Pre- Filled Normal Saline Flush Syringe is a three-piece, sterile, single use syringe with a 6% (Luer) connector pre-filled with 0.9% Sodium Chloride Injection, USP, and sealed with a tip cap.	Identical
Design	Flush Syringe (Prefilled 0.9% normal saline solution) with Luer lock connection fitting and non-vented, female Luer lock tip cap	Prefilled Normal Saline plastic piston syringe with Luer lock connection fitting and non-vented, female Luer lock tip cap	Identical
Chemical composition	0.9% Sodium chloride injection, USP	0.9% Sodium chloride injection, USP	Identical
Syringe material	Barrel and plunger: polypropylene Stopper: Bromo Butyl rubber (not made with natural rubber latex) Tip cap: polypropylene with white colorant	Barrel and plunger: polypropylene Stopper: Butyl rubber (not made with natural rubber latex) Tip cap: polypropylene with white colorant	Identical
Syringe Size and Fill Volumes	Fill 3ml, 5ml, 10ml volume in 10cc syringe	Fill 3ml, 5ml, 10ml volume in 12cc syringe Fill 20ml volume in 20cc syringe	Different (Comment 1)
Fill Volume Graduation	On syringe label	On syringe label	Identical

Syringe Content	0.9% Sodium Chloride Injection, USP	0.9% Sodium Chloride Injection, USP	Identical
Syringe packaging	Polyster & LD ribbon pouch Sterile barrier	PP wrap or Sterile barrier Plastic peel pouch	Different (Comment 2)
Sterile	Yes	Yes	Identical
Device with Fluid path only sterile Or Device provided sterile	Device with Fluid path only sterile and Device provided sterile	Device with Fluid path only sterile Or Device provided sterile	Identical
Sterilization method and SAL Level	Terminally sterilized by Gamma radiation, 10^{-6} SAL	Terminally sterilized by Gamma radiation, 10^{-6} SAL	Similar
Labeled non-pyrogenic	Yes	Yes	Identical
Single use only	Yes	Yes	Identical
Shelf Life	3 years	2 years	Different (Comment 3)
Content of Syringe Package	One syringe per pouch	One syringe per pouch	Identical

Comment 1: The subject device has range 3ml, 5ml & 10 ml which is similar to predicate device, predicate device has additionally Fill 20ml volume in 20cc syringe, the device capacity is based on device intended use, it does not impact intended use. Fill volume according to the market needs.

Comment 2: Subjective device has different pouch packing with comparison of predicate device, package integrity tests is conducted, different pack size does not impact on intended usage of product.

Comment 3: Subjective device has 3 years shelf life while predicate device has 2 years; stability study is conducted to justify the shelf life. It does not impact the intended usage and product Quality.

g) Summary of Non-clinical Testing (Bench):

The non-clinical testing for Flush Syringe (Prefilled 0.9% normal saline solution) was performed to demonstrate verification testing in conformance with the acceptance criteria of test methods and recognized consensus standards shown below.

The following performance testing was conducted on the proposed device:

Table 5-2

ID#	Test	Method	Acceptance criteria	Conclusion
1	Physical testing of syringe	ISO 7886-1, ISO 11040-8, ISO 80369-7	ISO7886-1 ISO80369-7	Pass
	Integrity test of package	ASTM F2338-09	No leakage	Pass
	Dimension test	ISO 80369-7	ISO80369-7	Pass
	Lubricant of syringe test	ISO 7886-1	ISO7886-1	Pass
	Dead space test	ISO 7886-1	ISO7886-1	Pass
	Limits of acidity or alkalinity of syringe	ISO 7886-1	ISO7886-1	Pass
2	**Sodium Chloride Injection, USP Testing**			
	pH value	USP<791>	PH: 4.5-7.0	Pass
	Chemical Identification Tests	USP<191>	USP<191>	Pass
	0.9% normal saline content test	USP 6-466	0.86% - 0.94%	Pass
	Oxidizable substance test	VP200	VP200	Pass
	Iron test	USP<241>	＜2ppm	Pass
	Ammonium	USP<191>	USP<191>	Pass
	Calcium	USP<191>	USP<191>	Pass
	Carbonate	USP<191>	USP<191>	Pass
	Sulfate	USP<191>	USP<191>	Pass
	Total organic carbon	USP<643>	USP<643>	Pass
	Limits of extractable metals	USP<233> USP<232>	USP<233> USP<232>	Pass
3	Particulate matter	USP<788>	≥10um, ≤6000 ≥25um, ≤600	Pass
4	**Biocompatibility testing:**			
	Bacterial endotoxins test	USP<85>	Bacterial endotoxins≤0.5EU/mL	Pass
	Acute systemic toxicity	ISO10993-11	No acute systemic toxicity	Pass

	Intra-cutaneous reactivity	ISO10993-10	Non-irritant	Pass
	Skin sensitization	ISO10993-10	Non-sensitizer	Pass
	In vitro cytotoxicity	ISO10993-5	Non-cytotoxic	Pass
	Material Mediated Pyrogenicity	ISO 10993-11	No pyrogenicity	Pass
	Genotoxicity (Bacterial Reverse Mutation Test)	ISO 10993-3	No Genotoxicity	Pass
	Implantation	ISO 10993-6	No evidence of local tissue effects	Pass
	In vitro hemolysis properties	ASTM F756-17	Non-hemolytic	Pass
5.	**Package Integrity Test**			
	Sealing Strength	ASTM F88/F88M and EN 868-5	Should not be less than 1.2N	Pass
	Dye Penetration Test	ASTM F 1929	Should be no evidence of leakage	Pass
	Vacuum decay test	ASTM F 2338	There should be no water present inside the pouch	Pass

The shelf life of the final finished sterilized device was evaluated according to the recognized consensus standard ASTM F1980-16 to verify that the subject device will remain within specification during the prescribed shelf life when stored under the labeled storage conditions.

h) Conclusions:

The conclusions drawn from the nonclinical tests demonstrate that the Flush Syringe (Prefilled 0.9% normal saline solution) is as safe, as effective, and performs as well as or better than the legally marketed predicate device.